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IVQ-003RCE**REMARKS**

In the foregoing amendments, claims 1, 22 and 26 have been amended. Claims 1-51 are currently pending, of which claims 1, 22, 26, 33, 42, 47 and 51 are independent. No new matter has been added.

**I. Telephone Interview with the Examiner**

Applicants thank the Examiner for the telephone interview conducted with the Examiner on March 7, 2007. The topic of the interview focused on the 35 U.S.C. §102(b) rejections concerning the "integrated electronic instrumentation" as recited in claims 1-31, 33-41 and 51. The Examiner indicated that the term "integrated electronic instrumentation" could be construed so as to read on United States Patent Number 6,682,440 to Karidis et al (hereafter "Karidis"). However, the Examiner did indicate that the Karidis reference does not anticipate electronics *incorporated into a paper diary*.

**II. Claim Amendments**

In view of the interview with the Examiner, Applicants have amended independent claims 1 and 22 to recite "integrated electronic instrumentation incorporated into the paper diary." Similarly, Applicants have amended independent claim 26 to recite "electronic device for incorporation into a paper diary." No new matter has been added. Applicants believe that the above claim amendments address the issues raised by the Examiner during the interview, and contend that the claims as amended do not read on the Karidis reference, as will be explained below.

**III. Claim Rejections under 35 USC §102**

The Examiner rejected claims 1-31, 33-41 and 51 under 35 U.S.C. §102(b) as being anticipated by Karidis (Office Action, paragraphs 2-3). Applicants respectfully traverse the rejection for the reasons set forth below.

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A. Claim 1

Applicants respectfully submit that Karidis fails to disclose at least the following element of amended independent claim 1: “integrated electronic instrumentation *incorporated into the paper diary* for generating an electronic record containing information regarding use of the paper diary.” As will be explained in more detail below, this is not disclosed by Karidis.

Applicants’ invention provides a paper diary for recording information in a clinical trial and monitoring subject compliance with research and medical protocols. As recited in amended claim 1, usage information is recorded with electronic instrumentation *incorporated into the paper diary*. In contrast, the subject matter of the Karidis reference is a *computer* with a recording unit. The computer of Karidis is not the same as the instrumented paper diary of the present invention. The paper diary of the present invention is different in structure, functionality, and use.

The Examiner identified column 13, lines 35-40 in the Karidis reference (Office Action, paragraph 3) as disclosing a “paper form for recording data with an integrated electronic instrument that generates a record regarding the use of the paper diary (form).”

The cited sections of Karidis fail to disclose “integrated electronic instrumentation incorporated into the paper diary,” as required by amended claim 1. Rather, the cited sections discuss a step in the logic used to accomplish synchronization of information as well as switching between landscape and portrait modes in connection with Figure 15.

Karidis does not disclose “integrated electronic instrumentation *incorporated into the paper diary*,” as recited in amended claim 1. First, the Karidis apparatus is a portable computing device with a recording unit, not a paper diary. Applicants’ amended claim 1 recites a specific type of diary, i.e. a *paper diary*, which has a very common and recognizable form. In contrast, Karidis discusses a computing device that includes a recording unit. Applicants draw the Examiner’s attention to Applicants’ Figure 1 which illustrates a recognizable *paper diary*, in contrast to Figures 2-3 in Karidis which clearly show a *computer augmented with a recording unit*. Applicants thus contend that the Karidis apparatus is not synonymous with a paper diary.

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Second, Karidis does not disclose incorporation of electronic instrumentation into the paper diary. Karidis states that the recording unit of the computing device records a time and date stamp indicative of the time and date of an event (Karidis, column 10, lines 17-19). Thus, the recording unit is the electronic instrumentation for recording usage data in Karidis. Karidis fails to disclose that this recording unit is incorporated into the note-taking surface of the apparatus. Rather, Karidis states that the recording unit includes a working surface which is super-imposable with a *removable markable surface*, e.g. paper (Karidis, column 2, lines 24-26). Clearly, the electronic instrumentation of the recording unit is not incorporated into the markable surface which is removable. Thus, Karidis fails to disclose "integrated electronic instrumentation *incorporated into the paper diary*," as required by amended claim 1.

The instrumented paper diary of the present invention further provides several advantages over the computer based system of Karidis.

Applicants' amended claim 1 is directed to an instrument paper diary. The recognizable form of this paper diary is illustrated in Applicants' Figure 13. In many instances the use of a paper diary is more convenient than the computer based system of Karidis. Applicants' paper diary is smaller, lighter, and more portable than the Karidis apparatus. This means it is much easier for a clinical trial participant to keep the paper diary with them for recording data throughout the day.

A paper diary is also a more natural and easy-to-use means of recording trial data. People conventionally take quick notes in a paper diary, which is easy to open, flip through and close. Using a computer for recording trial data requires a certain level of familiarity with a computer that is not required to use a paper diary.

Lastly, instrumentation integrated into a paper diary allows a more discreet means of recording trial data than a computer. In one embodiment of the claimed invention, the integrated electronics may be hidden from the trial participant, and the participant will not be aware that they are being monitored. In contrast, a participant using a computer will be aware that data entry is being constantly monitored by the computer.

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Based on the foregoing arguments, Applicants contend that the instrumented paper diary of the present invention is distinguishable from the computer based system of Karidis and provides several advantages of such a computer based system.

In view of the foregoing amendments and arguments to claim 1, Applicants respectfully request reconsideration and allowance of amended claim 1.

**B. Claims 2-21**

Claims 2-21 depend from amended independent claim 1 and, as such, incorporate all of the features of amended claim 1. As discussed above, amended claim 1 is allowable over Karidis. Accordingly, claims 2-21 are also allowable for at least the reasons set forth above with respect to amended claim 1. Applicants respectfully request reconsideration and allowance of claims 2-21.

**C. Claim 22**

Applicants respectfully submit that Karidis fails to disclose at least the following element of amended independent claim 22: "an instrumented paper diary including paper forms allowing a subject to enter data and integrated electronic instrumentation *incorporated into the paper diary* for generating an electronic record of paper diary use."

The Examiner identified column 13, lines 35-40 in the Karidis reference (Office Action, paragraph 3) as disclosing a "paper form for recording data with an integrated electronic instrument that generates a record regarding the use of the paper diary (form)." As discussed previously in connection with amended claim 1, the cited section is not directed to the subject matter of Applicants' claims. Karidis fails to disclose "integrated electronic instrumentation incorporated into the paper diary," as required by amended claim 22.

As discussed above, Applicants' instrumented paper diary is smaller, easier to use, and can be more discreet than the computer system of Karidis. Thus, Applicants contend that Applicants' invention provides a novel means of recording trial data using an instrumented paper diary that is more practical than using a computer for the same purpose. Applicants submit that

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the arguments set forth above with respect to amended claim 1 are also applicable to amended claim 22.

In view of the foregoing amendments and arguments to claim 22, Applicants respectfully request reconsideration and allowance of amended claim 22.

**D. Claims 23-25**

Claims 23-25 depend from amended independent claim 22 and, as such, incorporate all of the features of amended claim 22. As discussed above, amended claim 22 is allowable over Karidis. Accordingly, claims 23-25 are also allowable for at least the reasons set forth above with respect to amended claim 22. Applicants respectfully request reconsideration and allowance of claims 23-25.

**E. Claim 26**

Applicants respectfully submit that Karidis fails to disclose at least the following element of amended independent claim 26: "an electronic device *for incorporation into a paper diary*, wherein the electronic device generates an electronic record tracking clinical trial data." As will be explained in more detail below, this element is not disclosed by Karidis.

The Examiner identified column 13, lines 35-40 in the Karidis reference (Office Action, paragraph 3) as disclosing a "paper form for recording data with an integrated electronic instrument that generates a record regarding the use of the paper diary (form)." As discussed previously in connection with amended claim 1, the cited section is not directed to the subject matter of Applicants' claims.

Applicants' invention as recited in amended claim 26 provides an electronic device that tracks clinical trial data for incorporation into a paper diary. In contrast, as illustrated in Figures 2-3, the electronic device in the Karidis reference is clearly a portable computing device with a recording unit. Karidis does not discuss a paper diary. Specifically, Karidis does not disclose that the electronic device used for recording data is meant for incorporation into a paper diary. Thus, Karidis fails to disclose "an electronic device *for incorporation into a paper diary*,

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wherein the electronic device generates an electronic record tracking clinical trial data," as recited by amended claim 26.

As discussed above, Applicants' instrumented paper diary is smaller, easier to use, and can be more discreet than the computer system of Karidis. Thus, Applicants contend that Applicants' invention provides a novel means of recording trial data using an instrumented paper diary that is more practical than using a computer for the same purpose. Instrumented paper diary is smaller, cheaper, easier to use and can be more discreet than a computer. Thus, Applicants contend that Applicants' invention provides a novel means of recording trial data using an instrumented paper diary that is more practical than using a computer for the same purpose. Applicants submit that the arguments set forth above with respect to amended claim 1 are also applicable to amended claim 26.

In view of the foregoing amendments and arguments to claim 26, Applicants respectfully request reconsideration and allowance of amended claim 26.

**F. Claims 27-31**

Claims 27-31 depend from amended independent claim 26 and, as such, incorporate all of the features of amended claim 26. As discussed above, amended claim 26 is allowable over Karidis. Accordingly, claims 27-31 are also allowable for at least the reasons set forth above with respect to amended claim 26. Applicants respectfully request reconsideration and allowance of claims 27-31.

**G. Claim 33**

Applicants respectfully submit that Karidis fails to disclose at least the following element of independent claim 33: "detecting an event related to data entry in a paper diary for recording data using electronic instrumentation *incorporated into the paper diary*."

The Examiner identified column 15, lines 35-40 in the Karidis reference (Office Action, paragraph 17) as disclosing a "a method of detecting an event related to data entry onto paper with an electronic instrument incorporated it[sic] diary." The cited sections of Karidis fail to disclose "detecting an event related to data entry in a paper diary for recording data using

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electronic instrumentation *incorporated into the paper diary*," as required by claim 33. Rather, the cited sections discuss that a user may concurrently and cooperatively use both the recording unit and keyboard of the computing device. The cited sections do not include any mention of a paper diary. More specifically, the sections do not disclose that data is recorded using "electronic instrumentation incorporated into the paper diary," as required by claim 33.

As discussed above, Applicants' instrumented paper diary is smaller, easier to use, and can be more discreet than the computer system of Karidis. Thus, Applicants contend that Applicants' invention provides a novel means of recording trial data using an instrumented paper diary that is more practical than using a computer for the same purpose. Applicants submit that the arguments set forth above with respect to amended claim 1 are also applicable to claim 33.

In view of the foregoing arguments to claim 33, Applicants respectfully request reconsideration and allowance of claim 33.

#### H. Claims 34-41

Claims 34-41 depend from independent claim 33 and, as such, incorporate all of the features of claim 33. As discussed above, claim 33 is allowable over Karidis. Accordingly, claims 34-41 are also allowable for at least the reasons set forth above with respect to claim 33. Applicants respectfully request reconsideration and allowance of claims 34-41.

#### I. Claim 51

Applicants respectfully submit that Karidis fails to disclose at least the following element of independent claim 51: "incorporating said electronic instrumentation into the paper diary to record when the diary is in use."

The Examiner identified column 13, lines 35-40 in the Karidis reference (Office Action, paragraph 3) as disclosing a "paper form for recording data with an integrated electronic instrument that generates a record regarding the use of the paper diary (form)." As discussed previously in connection with claim 1, the cited sections are not directed to the subject matter of Applicants' claims. Karidis fails to disclose "incorporating said electronic instrumentation into the paper diary," as required by claim 51.

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As discussed above, Applicants' instrumented paper diary is smaller, easier to use, and can be more discreet than the computer system of Karidis. Thus, Applicants contend that Applicants' invention provides a novel means of recording trial data using an instrumented paper diary that is more practical than using a computer for the same purpose. Applicants submit that the arguments set forth above with respect to amended claim 1 are also applicable to claim 51.

In view of the foregoing arguments to claim 51, Applicants respectfully request reconsideration and allowance of claim 51.

#### **IV. Claim Rejections under 35 USC §103**

##### **A. Claims 47 and 48**

The Examiner rejected claims 47 and 48 under 35 U.S.C. §103(a) as being unpatentable over Karidis (Office Action, paragraph 20). Applicants respectfully traverse the rejection for the reasons set forth below.

Karidis has been summarized above. Karidis fails to teach or suggest "tracking the subject's use of the instrumented paper diary using electronic instrumentation *incorporated into the instrumented paper diary*," as required by claims 47 and 48.

The Examiner identified column 15, lines 35-40 in the Karidis reference (Office Action, paragraph 21) as teaching a "a method of detecting an event related to data entry onto paper with an electronic instrument incorporated it[sic] diary." As discussed previously in connection with claim 33, the cited sections are not directed to the subject matter of Applicants' claims. Karidis fails to teach or suggest "electronic instrumentation incorporated into the instrumented paper diary," as required by claims 47 and 48. Since Karidis does not include any mention of a paper diary, Applicants also contend that Karidis fails to motivate the incorporation of electronic instrumentation into such a paper diary, as required by Applicants' claims 47 and 48.

As discussed above, Applicants' instrumented paper diary is smaller, easier to use, and can be more discreet than the computer system of Karidis. Thus, Applicants contend that Applicants' invention provides a novel means of recording trial data using an instrumented paper diary that is more practical than using a computer for the same purpose. Applicants submit that

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the arguments set forth above with respect to amended claim 1 are also applicable to claims 47 and 48.

In view of the foregoing arguments to claims 47 and 48, Applicants respectfully request reconsideration and allowance of claims 47 and 48.

**B. Claims 42-46**

The Examiner rejected claims 42-46 under 35 U.S.C. §103(a) as being unpatentable over Karidis as applied to claims 47-48, and further in view of non-patent literature "Diary keeping in asthma: comparison of written and electronic methods" by Hyland et al (hereafter "Hyland") (Office Action, paragraph 23). Applicants respectfully traverse the rejection for the reasons set forth below.

Karidis has been summarized above. Karidis fails to teach or suggest "generating an electronic record containing information regarding use of a paper diary for recording clinical trial data using electronic instrumentation *incorporated into the paper diary*," as required by claims 42-46.

The Examiner identified column 15, lines 35-40 in the Karidis reference (Office Action, paragraph 24) as teaching "detecting an event related to data entry onto paper with an electronic instrument incorporated it[sic] diary." As discussed previously in connection with claim 33, the cited sections are not directed to the subject matter of Applicants' claims, and fail to teach or suggest "electronic instrumentation incorporated into the paper diary," as required by claims 42-46. Since Karidis does not include any mention of a paper diary, Applicants also contend that Karidis fails to motivate the incorporation of electronic instrumentation into such a paper diary, as required by Applicants' claims 42-46.

The teachings of Hyland do not supplement Karidis in such a way as to cure the failure to recite the above element of claims 42-46. Hyland discusses comparing an electronic diary and a paper diary to determine the extent to which symptom diaries of asthmatic patients are inaccurate or based on retrospective recall (Hyland, abstract). In contrast, Applicants' claims 42-46 require generating an electronic record using electronic instrumentation incorporated into

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the paper diary. Hyland fails to teach or suggest “electronic instrumentation *incorporated into the paper diary*.” Rather, Hyland discusses separate electronic and paper diaries. Applicants thus respectfully submit that claims 42-46 are not rendered obvious by the combination of Karidis and Hyland because Hyland does not cure the deficiency left by Karidis with regard to the aforementioned elements of claims 42-46.

In view of the foregoing arguments to claims 42-46, Applicants respectfully request reconsideration and allowance of claims 42-46.

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**CONCLUSION**

In light of the above, Applicants submit that all of the pending claims 1-51 are in condition for allowance. Should the Examiner feel that a teleconference would expedite the prosecution of this application, the Examiner is urged to contact the Applicants' attorney at (617) 227-7400.

Please charge any shortage or credit any overpayment of fees to our Deposit Account No. 12-0080, under Order No. IVQ-003RCE. In the event that a petition for an extension of time is required to be submitted herewith, and the requisite petition does not accompany this response, the undersigned hereby petitions under 37 C.F.R. §1.136(a) for an extension of time for as many months as are required to render this submission timely. Any fee due is authorized to be charged to the aforementioned Deposit Account.

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Respectfully submitted,

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